PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

RETIN-A® 0.05 % cream

RETIN-A® 0.025 % gel

Each one gram of cream contains 0.5 mg of the active ingredient, tretinoin and sorbic acid 0.2 % m/m as preservative.

Each one gram of gel contains 0.25 mg of the active ingredient, tretinoin.

Read all of this leaflet carefully before you start using RETIN-A® because it contains important information for you:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- RETIN-A® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What RETIN-A® is and what it is used for
2. What you need to know before you use RETIN-A®
3. How to use RETIN-A®
4. Possible side effects
5. How to store RETIN-A®
6. Contents of the pack and other information

1. What RETIN-A® is and what it is used for

RETIN-A® is a topical preparation.

RETIN-A® is used in the treatment of hyperkeratotic (thickening of the skin) follicular and related conditions such as *acne vulgaris* where comedones, papules and pustules are present.

RETIN-A® is used as additional therapy for the topical treatment of uneven patches of skin, roughness, and fine wrinkling of photodamaged skin due to chronic sun exposure in patients who do not respond to comprehensive skin care programs and sun avoidance measures.

There is no convincing evidence that RETIN-A® permanently removes wrinkles, repairs sun-damaged skin, reverses photo-aging, or restores a more youthful dermatological pattern.

2. What you need to know before you use RETIN-A®

Do not use RETIN-A®:

- If you are hypersensitive (allergic) to tretinoin or any of the other ingredients of RETIN-A® (listed in section 6).
- if you have ever had a tumour on the top layer of your skin, or if this condition runs in your family.
- if you have inflamed, red, dry, and scaly skin (eczema).
- if you have a skin problem which can cause redness of the cheeks, nose, chin or forehead (acne rosacea).
- if the skin around your mouth is irritated (peri-oral dermatitis).
- if you have sunburn or skin irritation with redness, peeling or itching. Your skin will need time to recover from this before you start using RETIN-A®.
- if you have been using a skin peeling agent (which removes the top layers of your skin). Your skin will need time to recover before you start using RETIN-A®.
- if you are pregnant or breastfeeding (see Pregnancy and breastfeeding).

Warnings and Precautions

Take special care with RETIN-A®

- It is not recommended to initiate treatment with RETIN-A® or continue its use in the presence of skin irritation (e.g., abnormal redness, peeling, itching, sunburn, etc.). If the degree of local irritation warrants, you should apply the medication less frequently or discontinue its use temporarily.
- RETIN-A may induce swelling, local redness, itching, warmth, burning or stinging, blistering crusting and/or peeling at the site of application.
- RETIN-A® has been reported to cause severe irritation on eczematous skin (i.e., Inflamed skin characterised by redness, itching and the outbreak of lesions) and should be used with utmost caution in patients with this condition.
- If you experience severe or persistent irritation, whilst using RETIN-A, you Should discontinue application of RETIN-A completely, and consult a medical practitioner.
- Weather extremes, such as wind, cold and low humidity may be irritating to skin treated with RETIN-A and may increase its dryness.
- Avoid or minimize exposure to sunlight, including ultraviolet sunlamps while using RETIN-A. If you are sunburned, do not use RETIN-A until you are fully recovered. Exercise particular caution if you experience considerable sun exposure due to occupational duties and/or are inherently sensitive to the sun.
- If you cannot avoid exposure to sunlight, you should use a sunscreen product and protective clothing over treated areas.
- Avoid contact with the eyes, eyelids, angles of the nose, mouth, mucous membranes or other areas where treatment is not intended, in order to minimise the potential for skin irritation.

Children and adolescents

Safety and effectiveness have not been established.

Other medicines and RETIN-A®

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Use RETIN-A® with caution if:

- You are using other topical medications at the same time.
- You are using toiletry preparations that have an abrasive, drying, or peeling effect, including soaps, shampoos, cosmetics, perfumes and astringents (especially those containing benzoyl peroxide, sulphur, resorcinol, salicylic acid, alcohol, lime or spice).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using RETIN-A®.

Driving and using machines

RETIN-A® should not affect your ability to drive or use machines.

RETIN-A® contains:

- Stearyl alcohol and Sorbic Acid (E200) which may cause local skin reactions (e.g. contact dermatitis).
- Butylated hydroxytoluene which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

3. How to use RETIN-A®

Do not share medicines prescribed for you with any other person.

Always use RETIN-A® exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure.

- For topical administration only.
- Apply once daily in the evening and only a sufficient quantity to cover the affected areas lightly.
- Cleanse the areas to be treated thoroughly using a mild, non-medicated soap.

After cleansing, pat the skin dry without rubbing. Allow the area to dry for a period of 20-30 minutes before applying the RETIN-A®. Twice daily washing of the treated area is more than sufficient.

- Application of RETIN-A® may cause temporary stinging and a feeling of warmth.
- When RETIN-A® is applied, it normally produces a slight, momentary redness like that of mild sunburn.
- Do not apply RETIN-A® more frequently or in larger quantities than recommended, this will not improve the outcome of treatment and may induce marked skin irritation.
- Cosmetics and moisturisers may be used concurrently throughout the duration of RETIN-A® therapy.
- **Duration of treatment:** The onset of visible improvements is variable, however, in general, effects emerge after two to three weeks of therapy.
  Results may not be optimal until after 6 weeks of therapy. Once the acne lesions have responded satisfactorily; it may be possible to maintain the Improvement with less frequent applications.

Your doctor will tell you how long your treatment with RETIN-A® will last. Do not stop treatment early. If you have the impression that the effect of RETIN-A® is too strong or too weak, tell your doctor or pharmacist.

If you use more RETIN-A® than you should:

Topical application of RETIN-A® is characterised by little systemic absorption, hence overdosage from topical application is unlikely.

If RETIN-A® is accidentally swallowed, if the ingestion is recent, you should induce vomiting.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Excessive use does not increase therapeutic effects and may produce marked inflammatory reactions (e.g., erythema, peeling, pruritus, sunburn, etc).

If you forget to use RETIN-A®

Do not use a double dose to make up for forgotten individual doses.

4. Possible side effects

RETIN-A® has side-effects.

Not all side-effects reported for RETIN-A® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using RETIN-A®, please consult your health care provider for advice.

Symptoms of local irritation frequently reported during therapy include dry or peeling skin, burning, stinging, warmth, redness, itching, and temporary hypo- and hyperpigmentation. They usually occur early in therapy and, except for dry or peeling skin which may persist during therapy, generally decrease over

the course of treatment. Heightened sensitivity to either sunlight or other sources of UVB have been reported.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist, or nurse.

You can report side effects to the **MC Pharma Pharmacovigilance** department by e-mail to pharmacovigilance@mcpharma.co.za, or call 012 688 3019.

You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of RETIN-A®

5. How to store RETIN-A®

Store all medicines out of reach of children.

For external use only.

Do not use after the expiry date stated on the tube and carton. The expiry date refers to the last day of the month.

Store at or below 25 °C. Protect from light. Do not freeze.

Return all unused medicine to your pharmacist for proper disposal.

Do not dispose of unused medicine in drains and sewerage systems (e.g., toilets).

6. Contents of the pack and other information:

What RETIN-A® contains:

The active substance is tretinoin.

One gram of cream contains 0.5 mg of tretinoin and 0.2 % m/m sorbic acid as a preservative.

The other ingredients are polyoxy 40 stearate, stearyl alcohol, stearic acid, isopropyl myristate, butylated hydroxy-toluene, sorbic acid, xanthan gum, and purified water.

What RETIN-A® looks like and contents of the pack:

RETIN-A 0.05 % cream: Yellow, oil-in water cream having a faint waxy odour.

RETIN-A 0.025 % gel: Smooth, clear viscous yellow gel, having an odour of alcohol.

RETIN-A 0,05 % cream and 0.025 % gel is packed in screw-capped aluminium tubes containing 20 g.

Holder of the certificate of registration:

MC Pharma (Pty) Ltd

62 Constantia Avenue

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Customer Care: 012 668 3019

This leaflet was last revised in:

RETIN-A 0,05 %: Date of original registration – 09 October 1973

Date of Implementation of the latest PI/PIL update - 10 February 2026

Registration number:

RETIN-A 0,05 % cream F/13.12/106

RETIN-A 0.025% gel: J/13.12/350